IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Jorgen K. Smedegaard Confirmation No.: 5828

Application No.: 10/619,237 Group Art Unit: 3763

Filed: July 14, 2003 Examiner: BOUCHELLE, Laura A.

For: Medical Delivery Device

APPEAL BRIEF UNDER 37 C.F.R. § 41.37

Commissioner for Patents
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401 Dulany Street
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Sir:

This Appeal is from the Examiner's Final Rejection of claim 30 set forth in the Final Office Action mailed from the U.S. Patent and Trademark Office on January 11, 2008.

A Notice of Appeal in response to the January 11, 2008 Final Office Action was filed on May 12, 2008, as May 11, 2008 fell on a Sunday.

Payment in the amount of $ 540.00 is concurrently submitted as payment of the requisite fee under 37 C.F.R. § 41.20(b)(2), and payment in the amount of $2,350.00 is concurrently submitted as payment for the 5 month Extension of Time extending the time period for filing the Appeal Brief from July 11, 2008 to December 11, 2008. No additional fee is believed to be required for filing the instant Appeal Brief. However, if for any reason a necessary fee is required for consideration of the instant paper, authorization is hereby

given to charge the fee for the Appeal Brief and any necessary extension of time fees to Deposit Account No. 14-1447.

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I. REAL PARTY IN INTEREST

The real party in interest in this appeal is Novo Nordisk A/S, of Bagsvaerd, Denmark. The assignment was recorded in the U.S. Patent and Trademark Office on February 14, 2006 at REEL 014674, FRAME 0364.

II. RELATED APPEALS AND INTERFERENCES

Appellants, Appellants' representative or the Assignee are not aware of any other prior and pending appeals, interferences or judicial proceedings which may be related to, directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

III. STATUS OF CLAIMS

Claim 30 is pending. Claim 30 stand finally rejected. Thus, finally rejected claim 30 is at issue in the instant appeal and form the subject matter of the instant Appeal Brief and the cancelled claims do not stand or fall together. The claim in issue are attached in the "Claims Appendix".

IV. STATUS OF AMENDMENTS

An Amendment under 37 C.F.R. § 41.33(b)(1) is filed concurrently herewith, which cancels claims 32, 33, and 34 without prejudice or disclaimer, to simplify issues for appeal. Claim 31 has been previously cancelled and claims 1-29 have been previously withdrawn. Accordingly, the claims presented for appeal are those filed in the Amendment under 37 C.F.R. § 41.33(b)(1) filed concurrently herewith.

V. SUMMARY OF CLAIMED SUBJECT MATTER

A. Claim 30

Independent claim 30 is drawn to a method of treating a patient suffering from a disease by providing the patient with a device having a lower surface with an adhesive means to be attached to the skin surface of a patient and that delivers an insulin-containing drug to the patient slowly and over a period of 7-9 hours when the patient is expected to sleep and wherein the device is removed when the patient is expected to be awake so that the infusion ceases when the device is removed. In short, the claimed invention relates to a novel method of treating a patient in need of insulin therapy (i.e. , a patient with diabetes) by slowly infusing insulin over a 7-9 hour period when the patient is asleep and removing the infusion device and ceasing the infusion when the patient wakes up. The infusion takes place by attaching directly to a patient a drug delivery device capable of performing the infusion and when the patient wakes up the device is removed and the infusion ceases.

In this regard, exemplary embodiments of the present invention are shown in the specification in Figures 4 and 5, numerals 12, 20, and 65, and disclosed at page 5, lines 21 to 29.

VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

The broad issues under consideration are:

1. Whether claim 30 is properly rejected under 35 U.S.C. § 102(b) as being anticipated by Gross et al., U.S. Patent No. 5,848,991 (hereafter "GROSS");
2. Whether claim 30 is properly rejected in the alternative under 35 U.S.C. § 103(a) in view of GROSS.

VII. ARGUMENTS

A. Summary of Rejections of Record

1. With regard to claim 30 rejected under 35 U.S.C. § 102(b) as being anticipated by GROSS, the rejection alleges that GROSS discloses a method of treating a patient with a disease comprising the steps of providing a delivery device having a lower surface with an adhesive means adapted to be attached to the skin of a patient, delivering a therapeutic agent to the patient during a period of sleep, and removing the device after a period of sleep. The Examiner admits that GROSS does not teach the device delivers fluid for a period of 7-9 hours but then further argues that GROSS discloses that the device delivers fluid during sleep which is either inherently or obviously approximately 7-9 hours. The Examiner, in her rejection under § 102(b), states that GROSS does disclose that the device is to be removed after sleep and cites without explanation to column 4 lines 55-65 which states:

> It is thus possible to choose or devise a dosage regime which will suit the requirements of both the individual patient and of the drug to be delivered. For example, the device may comprise a microprocessor which controls delivery such that the rate of delivery is varied during a 24 hour cycle as is necessary due to the differing requirements of drug dosage during periods of activity, inactivity and sleep, and taking account of the subject's requirements in relation to food intake."

The Examiner, however, does not cite to any passage in GROSS where it states that would be advisable "to choose or devise" an ***insulin therapy regime*** where the awake-time

insulin requirement would go to zero --such that the GROSS device can be removed when the patient is awake-- and where the sleep-time requirement is greater than zero --such that the device is re-applied to deliver insulin slowly and over a 7 to 9 hour period when the patient is asleep.

The rejection further alleges that GROSS discloses a reservoir can hold 0.2-10mL of fluid which is capable of containing 5-50 IU insulin. Ostensibly this argument relates to claim 32, which has been cancelled for purposes of this appeal.

2. With regard to claim 30 rejected under 35 U.S.C. § 103(a) as being obvious, the Examiner states --without supporting citation-- that it would have been obvious to apply the device of GROSS only when the patient requires a drug, such as overnight for a patient with mild dependence of insulin.

B. Citation of Authority

Under 35 U.S.C. § 102, "[a] claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987).

"[A]n invention is anticipated if the same device, including all the claim limitations, is shown in a single prior art reference. Every element of the claimed invention must be literally present, arranged as in the claim." *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236 (Fed.Cir. 1989) (citing *Perkin-Elmer Corp. v. Computervision Corp.*, 732 F.2d 888, 894 (Fed. Cir. 1984); *Kalman v. Kimberly-Clark Corp.*, 713 F.2d 760, 771-72 (Fed. Cir. 1983)). "[A]bsence from the reference of any claimed element negates anticipation." *Kloster Speedsteel AB v. Crucible, Inc.*, 793 F.2d 1565, 1571 (Fed. Cir. 1986).

In a 35 USC § 103(a) obviousness inquiry, pursuant to the Supreme Court's analysis in *Graham* v. *John Deere Co.*, 383 U.S. 1, 17-18 (1966), 'the scope and content of the prior art are to be determined, differences between the prior art and the claims at issue are to be ascertained; and the level of ordinary skill in the pertinent art resolved." The appropriate test is whether the invention, *as a whole*, would have been obvious or nonobvious." *Jones* v. *Hardy*, 727 F.2d 1524, 1529 (Fed. Cir. 1984). In seeking to establish a *prima facie* case of obviousness, the PTO may not rely on knowledge of Applicants' invention to "pick and choose" among disclosures in the prior art to deprecate the claimed invention. *In re Fine*, 837 F.2d 1071,1075, 5 U.S.P.Q.2d 1596, 1600 (Fed. Cir. 1988).

C. Claim 30 Is Not Properly Rejected Under 35 U.S.C. § 102(b) as Being Anticipated by GROSS.

As noted above, a rejection under 35 U.S.C. § 102 can only be maintained if every element of the rejected claim is found in a single prior art document. The requirement that all the claimed elements be taught or suggested in the cited document has not been met. Here, claim 30 requires explicitly "delivering a therapeutic amount of the **insulin**-containing drug during a period of approximately 7-9 hours," wherein the 7-9 hour period of time during the infusion "**substantially correspond[s] to "the period of sleep"** and wherein **delivery of the insulin containing drug is discontinued after the 7-9 hour period** and **the device is removed**. GROSS does not teach that the device should be used only during sleep and removed during awake-time and GROSS does not teach that it is desirable to infuse **insulin** during **sleep-time only**. In summary, the claim requires sleep-time only infusion and that the sleep-time only infusion be of an insulin-containing drug. These elements are not in disclosed or suggested by GROSS.

1. No Disclosure of Sleep-Time Only Drug Infusion in GROSS

GROSS states that the disclosed drug delivery device "may comprise a microprocessor which controls the delivery such that the rate of delivery is varied during a 24 hour cycle as is necessary due to the differing requirements of drug dosage during periods of activity, inactivity and sleep, and taking account of the subject's requirements in relation to food intake", see column 4, lines 55-63. In other words, the Gross et al device may be in the form of an "advanced" drug delivery device providing the same programmability as the type of insulin pumps mostly used for the treatment of Type 1 diabetes, e.g. as supplied by Medtronic.

In the next paragraph it is stated that "alternatively (emphasis added), the subject may be provided with separate daytime and nighttime devices".

As follows from this, GROSS teaches that instead of a more complex device comprising a microprocessor, the patient may be supplied with two separate devices each having a different electronic circuit for controlling the time and rate of drug delivery for daytime respectively nighttime use, this allowing a patient to wear a device during all 24 hours of the day, albeit in the form of one device during daytime and another device during nighttime.

Although theoretically such a system would allow the patient to wear only a device during nighttime, there is absolute no disclosure or hint to be found in GROSS that would point the skilled person seeking to administer insulin therapy to use of the disclosed nighttime device only to infuse insulin slowly over a 7 to 9 hour period when the patient is asleep and to cease insulin infusion when the patient wakes up. Absent applicants' disclosure, the Examiner has pointed to no prior art in the Final Rejection

that indicates that it would be desirable to wear a device and infuse a drug only at sleep-time. This deficiency in GROSS is clearly seen by the fact that the Examiner has not cited to anything in GROSS that supports her position. Instead, she, attempts to argue that since GROSS discloses that the device can be used for fever treatment, it would only be worn when it is necessary. The Examiner, however, does not argue that GROSS (or any other document for that matter) suggestions only treating a fever at night. In fact, to bolster her argument, then Examiner then avers that there are a number of unspecified drugs that are to be administered only at nighttime, but the Examiner does not point to a single document disclosing any such drugs, which are designed to be infused by a device at nighttime sleep only. Indeed, the Examiner has not even argued that any of these undisclosed and unspecified drugs should be ***infused*** by a device for the entire period of sleep, which is about 7-9 hours as defined by claim 30; she has only alleged that a number of known, but unspecified, drugs are administered at night.

2. GROSS Does Not Disclose Sleep-Time Only Infusions of ***Insulin*** Lasting for a Period of 7 to 9 Hours and Being Terminated Upon Awaking

In GROSS it is disclosed that the device may be used to deliver a number of different drugs (including insulin), see column 6, line 42 to column 7, line 21, and it may thus be argued that the GROSS device may be used for periods of different length and for different infusion rates. However, there is no disclosure or teaching that any given type of drug should be infused during 7-9 hours and during a period of sleep. And most specifically, there is no disclosure or teaching that insulin should be infused slowly and only during 7-9 hours period of sleep as defined by the invention of claim 30.

In contrast and as applicants argued in their October 8, 2007 response to the July 6, 2007 Office Action applicant submits that when insulin is administered using a drug delivery device (i.e. in the form of a traditional type pump as provided by e.g. Medtronic) this is done solely for the treatment of patients suffering from diabetes Type 1 and thus for 24 hours. Treating diabetes patients with a body mounted drug delivery device with insulin during nighttime only is in contrast to all known regiments for the treatment of diabetes using a pump device and is neither disclosed nor hinted at in GROSS.

Indeed, the Examiner provides no citation to GROSS that supports the assertion that it is desirable to infuse ***insulin*** to a patient only during ***sleep time*** and to remove the device and hence ***stop the infusion*** during periods of awake-time. The Examiner has provided no citation within GROSS to a method of treating a patient with insulin by slowly infusing the insulin over a 7-9 hour sleep period. Without such a showing by the Examiner, a prima facie case of anticipation cannot be maintained.

D. **Claim 30 Is Not Properly Rejected Under 35 U.S.C. § 103(a) as Being Obvious in view of GROSS**

In the Final Office Action, the Examiner has made an unsupportable assertion that it would be obvious to infuse insulin at nighttime --and only at nighttime-- because "Gross discloses that the device might be used for a fever reducing drug . . . [and] [i]t is well known that fever is not a chronic condition and so clearly the device would not need to be worn continuously and would be removed between periods of use. It is clear that the device is meant to be used only when drug delivery is required and it is well known that for certain drugs delivery is only required during nighttime."

The Examiner's argument misses the boat. Even if it is obvious to infuse some drugs at nighttime and only at nighttime, why is it obvious to infuse **INSULIN** at nighttime only and to cease the infusion of insulin when the patient awakens?[1] By failing to point to prior art in the Final Rejection that suggests that nighttime only infusion of **insulin** (lasting 7 to 9 hours) is an appropriate and art recognized therapy, the Examiner has attempted to make GROSS --the only prior art relied upon in the Final Rejection-- fit the claims. It clearly does not. Moreover, the PTO cannot use the teaching of the Applicant as a reason to modify the reference. As set forth in more detail below, the failure of the Examiner to identify art that shows that those of skill in the art, *i.*e., those administering

[1] Indeed, it is entirely unclear how one would take the treatment of a non-chronic, acute condition such as a fever (which needs sporadic treatment when the fever appears) and extrapolate to the treatment of a chronic disease, such as diabetes, that needs *daily* insulin therapy. Moreover, it is even more unclear how the treatment of fever by administration of certain unspecified drugs at only nighttime would lead one of ordinary skill to adopt a nighttime (or sleep-time) only insulin infusion therapy and to make sure all insulin infusion was ceased during the day (or awake-time).

insulin therapy to a patient in need of insulin therapy, recognize slow nighttime only insulin therapy has a legitimate insulin treatment regime requires the withdrawal of her Final Rejection.

1. GROSS Does Not suggest a 7 to 9 Hour Insulin Infusion at Sleep-Time Only

The Examiner, while admitting that Gross does not teach to infuse of insulin only during an extended sleep period of 7-9 hours, avers that it would be obvious to do this since GROSS discloses that it may be desirable to deliver certain drugs only when required by the subject. The Examiner then makes the naked assertion that it would have been obvious to apply the device only when the patient requires the drug, such as overnight for a patient with a mild dependence of insulin. Under the *Graham* analysis, claim 30 is not obvious because, at the very least, the scope and content of the prior art cited by the Examiner do not contain the limitation that insulin should be infused over a 7-9 hour period of sleep. The Examiner has provided no support whatsoever that it is desirable to infuse insulin to a patient when the patient is in a sleep mode for 7-9 hours. Without support for this key assumption, the Examiner's obviousness rejection must be withdrawn.

Moreover, the Examiner has overlooked key differences between the claimed subject matter and has attempted to trivialize those differences. The Examiner, in the Final Office action, has asserted that GROSS teaches a separate daytime and nighttime device and that since the device can be tailored to a patient's needs the use of GROSS at nighttime only would be obvious because certain drugs are administered only at nighttime.[2] This argument, however, overlooks the key limitation in the claims that the drug to be

[2] The Examiner fails to provide even a single citation to anything that would support her assertion that it is well-known to deliver some drugs only at nighttime. And she provides no citation that infuse should be performed only at nighttime for these unnamed drugs. Infusion is narrower than drug delivery, as drug delivery occurs by taking a pill

infused contains insulin. The Examiner fails to address this key difference between the prior art (which here consists only of GROSS as the Examiner has not cited to anything else) and the claimed subject matters and therefore under the Supreme Court's analysis in *Graham*, the rejection cannot stand.

Applicants' note that the Examiner has also failed to state the relevant level of skill in the art. For example, to whom[3] would it be obvious to infuse slowly **insulin** only at nightly sleep-time? And why would that be obvious? Indeed, why is this obvious to the Examiner? No reasoning was provided by the Examiner in the Final Rejection, other than that the Examiner thinks one would infuse insulin at sleep-time in mildly insulin dependant patients. But unless the Examiner is offering expert medical testimony based on medical expertise, a factual basis for this assertion must be provided. And since no factual basis was provided, the rejection must be withdrawn.

2. Applicants' Disclosure Cannot Provide the Motivation to Modify Gross

Absent, Applicants' disclosure, the Examiner has not pointed to anything that would suggest that the device of GROSS should be worn only at a **sleep-time period of 7-9 hours** to infuse **insulin** during sleep. Indeed, nothing in the art cited by the Examiner in the Final Rejection suggests that it would even be obvious to try to infuse insulin over a 7-9 hour sleep-time period. The Examiner's only basis for arguing that it would be obvious to modify GROSS is because the Examiner believes it would be obvious to do so because it is

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or giving an injection.

[3] The Examiner has failed to state what the relevant level of skill in the art is. Is it a patient self-treating a condition that requires insulin therapy, or is it a medical professional prescribing treatment? It should be noted that human insulin is not a prescription product and can be purchased without a prescription. Thus, it would seem possible, that one of ordinary skill is a diabetic patient. And if the level of skill in the art is that possessed by the average diabetic patient, why would such a patient modify GROSS for nighttime only slow insulin infusion. If the level of skill is a prescribing medical professional, why would the medical professional select nighttime only insulin infusion? Nothing has been cited in the Final Rejection showing that a patient or a medical professional would adopt a

well-known for certain drugs delivery4 is only required at nighttime. The Examiner provides no basis and no citation to relevant medical professionals that suggest that nighttime or sleep-time only slow infusion of insulin over a 7 to 9 hour period is a recognized insulin therapy. Thus, one can only assume that the Examiner's suggestion to modify GROSS to infuse slowly insulin during sleep-time and to remove GROSS and stop infusion during awake-time comes from Applicants' disclosure.

* * * * * *

That the device of GROSS could be used to carry out the claimed method does not mean that the method as claimed in claim 30 is unpatentable. GROSS merely provides a means, which given the teaching of the present invention, may be used to perform an infusion of insulin over a 7-9 hour period. GROSS does not teach --or even hint-- to one of ordinary skill in the art who is trying to administer insulin therapy to a patient that nighttime only or sleep-time only infusion has any advantages over the prior art. That lack of teaching is fatal to the Examiner's rejection.

nighttime only insulin infusion.

4 Even if delivery is required for certain drugs at night-time, such as a sleeping pill, there is nothing in the Final Rejection that suggests infusion at nighttime only. Indeed, that key part of the invention is missing from the prior art relied upon by the Examiner.

VIII. CONCLUSION

Appellants respectfully submit that the Examiner has failed to point out in a single prior art reference each and every element as set forth in pending claim 30, which is a prerequisite for maintaining a rejection under 35 U.S.C. § 102. Moreover, claim 30 is not obvious in view of GROSS as there is absolutely no teaching in GROSS as to why it would be desirable to infuse **insulin** over a period of 7-9 hours coinciding with a sleep period for a patient --**and only during that sleep period and not during awake-time for the patient**. GROSS simply does not teach or even hint at the claimed method which relates to insulin therapy comprising nighttime or sleep-time only insulin infusion during a 7-9 hour sleep period and stopping insulin infusion by removing the device during awake-time. The Examiner's naked assertions about modifying GROSS are based on nothing more than hindsight application of the Applicants' disclosure to GROSS in order to make GROSS fit the claims. It is, therefore, respectfully requested that the Board reverse the Examiner's decision to finally reject claim 30, and to allow the application to issue in its present form.

Respectfully submitted,

Date: December 9, 2008

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23650
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CLAIM(S) APPENDIX

30. A method for the treatment of a patient suffering from a disease, comprising the steps of:

- providing a delivery device adapted to deliver an amount of an insulin-containing drug, the delivery device comprising a lower surface provided with adhesive means and adapted to be arranged against and attached to a skin surface of the patient,
- at a given time attaching the delivery device to a skin surface of the patient and

establish a fluid communication between the delivery device and the body of the patient,

- delivering a therapeutic amount of the insulin-containing drug during a period of approximately 7-9 hours, and
- discontinuing delivery of the insulin-containing drug to the patient after approximately 7-9 hours and removing the delivery device from the skin surface of the patient,
- wherein the fluid communication is established at a time after which the patient is expected to sleep for a period of approximately 7-9 hours, the insulin-containing drug being infused substantially corresponding to the period of sleep, and
- wherein no delivery device is attached to a skin surface of the patient during a period between two periods of sleep of approximately 7-9 hours.

EVIDENCE APPENDIX

None.

RELATED PROCEEDINGS APPENDIX

None.